REMARKS

Claims 29-47 and 50-60 are pending in this application. Claims 48-49 have been withdrawn for consideration as being drawn to a nonelected invention. Claims 1-28 have previously been cancelled without prejudice or disclaimer. Claims 29, 50 and 53 have been amended.

Supervisory Examiner Marschel is thanked for conducting a telephone interview with the undersigned attorney on August 17, 2010. During the interview, Supervisory Examiner Marschel agreed that amending the claims to recite, in part, "...wherein glycolide is a cyclic dimer of glycolic acid," would be supported in the specification and would likely render the claims allowable.

In view of the foregoing, claims 29, 50 and 53 have been amended to recite, in part, the following: "...wherein glycolide is a cyclic dimer of glycolic acid." Support for amended claims 29, 50 and 53 appears throughout the specification and claims as originally filed. No new matter has been added.

Applicants, by cancelling or amending any claims during the course of prosecution in this application, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert the full and/or original scope of any claim cancelled or amended herein later in prosecution and/or in a continuing application.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 29-47 and 50-60 have been rejected under 35 USC § 103(a) as being unpatentable over Kluger et al. in view of Fuisz, and further in view of Meyers ('731).

The Examiner asserts that "it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to modify Kluger et al. formulation by further replacing lactide by glycolide. Meyers discloses that lactide can be replaced by glycolide and vice versa." The Examiner further states that "the claimed invention which is a combination of two known solid organic acid polymers set forth prima facie obvious subject matter."

In response to Applicants arguments of October 23, 2009, the Examiner asserts the following: (i) that "Fuisz reference merely teaches that lactide and glycolide can be used interchangably without any physical changes in the composition. Applicant has used the same compounds lactide and glycolide in the instant claimed composition," (ii) that "If lactide and/or glycolide are referred to as polymers in Fuisz reference then they polymers in Applicants instant claimed composition. Lactide and glycolide can not be monomer in one invention and polymers in another invention," (iii) that Myers also teaches that the glycolide and lactide can be used interchangeably whether it is used in a film or a tampon as described above in length," and that (iv) "Kluger et al teaches lactide incorporated in the tampon for the desire pH 5.5 to be achieved the other references teach that the same effect can be reached by incorporating glycolide."

In view of the following, this rejection is respectively traversed.

At the outset, Applicants submit that the Meyers publication ('731), with regard to the disclosure of a pH modulated filim applied to delivery substrates such as tampons, is

entitled to rely ***only*** on the filing date of the 60/754,092 ('092) provisional application filed on December 27, 2005, which date is after our filing date of March 3, 2004.

Meyers ('731) was filed on December 14, 2006, as a Continuation-in-part of US application no. 10/074,272 (now US Patent no. 7,425,292) filed on February 14, 2002, which claims priority to provisional application 60/328,868 filed on October 12, 2001. Meyers '731 claims priority to the '272 application, the '092 provisional application, the '868 provisional application and provisional application no. 60/386,937 filed on June 7, 2002.

The disclosure in Meyers '731 of a pH modulated filim applied to delivery substrates such as tampons first appears in the Myers '092 provisional application and is ***NOT present in the '272 application or the '868 provisional application.*** Further, support does not appear to be present in the '937 provisional application. Accordingly, Meyers is ***not*** prior art against the present claims with regard to the pH modulated film disclosure. That is, Meyers is prior art against the present application only with regard to the disclosure supported by the '272 application, the '868 provisional application, and the '937 provisional application.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the

fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Independent claim 29 has been amended to recite "A catamenial tampon for insertion in a human vagina, comprising: (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, the formulation comprising 30-100 wt% of glycolide; optionally, 15-97 wt% of a solid organic acid; and optionally, 5-30 wt% of a wetting agent, based on the total weight of the formulation, ***wherein glycolide is a cyclic dimer of glycolic acid***." (emphasis added) Claims 29-49 each depend, directly or indirectly, from independent claim 29.

Independent claim 50 has been amended to recite "A catamenial tampon for insertion in a human vagina, comprising: (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) a formulation effective in reducing the pH in a menstruating vagina or in the catamenial tampon inserted therein to below pH 5.5 within one hour or less from the time of insertion, comprising 30-100% by weight of glycolide; optionally, 97-15% by weight of a solid organic acid; and optionally, 5-30% of a wetting agent, ***wherein glycolide is a cyclic dimer of glycolic acid***." (emphasis added) Claims 51-52 each depend directly from independent claim 50.

Independent claim 53 has been amended to recite "A catamenial tampon for insertion in a human vagina, comprising: (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; (c) a polymeric support provided between the inner core and the outer layer; and (d) a formulation deposited on the polymeric support, the formulation effective in reducing the pH in a menstruating vagina or in the catamenial tampon inserted therein to below pH 5.5, comprising 30-100% by weight of glycolide, optionally, 97-15% by weight of a solid organic acid, and optionally, 5-30% of a wetting agent, ***wherein glycolide is a cyclic dimer of glycolic acid***." Claims 54-60 each depend, directly or indirectly, from independent claim 53.

A. Kluger

Kluger is directed to a pH reducing formulation and delivery system for a tampon where the formulation **REQUIRES** a solid organic acid **POLYMER**, i.e., D,L-polylactic acid. *See* paragraph [0058]. Kluger **does not** teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed.

B. Fuisz

Fuisz is directed to a biodegradable controlled release flash flow melt-spun delivery system that can include specific **POLYMERS** marketed under the "Medisorb" and "Biodel" trademarks. Fuisz describes, at col. 7, that "Other specific polymers useful include those marketed under the Medisorb and Biodel trademarks. The Medisorb…identified as a "lactide/glycolide polymer"…The Biodel materials represent a family of various polyanhydrides which differ chemically." Fuisz **does not** teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed.

C. Meyers

Meyers is prior art ***only*** for the disclosure supported by the supported by the '272 application, the '868 provisional application, and the '937 provisional application. The disclosure regarding pH modulated films and pH modulated films applied to delivery substrates such as tampons, first appears in the Myers '092 provisional application filed on December 27, 2005. Accordingly, Meyers describes ***only*** thin film with non-self-aggregating uniform heterogeneity where the film can include polymers such as poly glycolic acid (PGA), polylactic acid (PLA), and lactide/glycolide copolymer. *See* paragraphs [0094], [0102] and [0103]. Meyers **does not** teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed.

The combination of Kluger, Fuisz, and Myers does not render the presently claimed subject matter obvious since none of Kluger, Fuisz and Myers teaches the use of glycolide

that is a cyclic dimer of glycolic acid, as presently claimed. Please *see* the arguments, regarding polymers versus monomers, set forth in Applicants Amendment and Response filed on October 23, 2009, and Applicants Response filed on July 12, 2010, each of which is incorporated herein by reference in its entirety.

D. Response to Examiner's Assertions (i) to (iv)

Regarding assertion (i), the Examiner asserts that "Fuisz reference merely teaches that lactide and glycolide can be used interchangeably without any physical changes in the composition. Applicant has used the same compounds lactide and glycolide in the instant claimed composition." As discussed previously at length, Fuisz is directed to a biodegradable controlled release flash flow melt-spun delivery system that can include specific **POLYMERS** marketed under the "Medisorb" and "Biodel" trademarks. Fuisz ***does not*** describe the use of the lactide which is a cyclic dimer of lactic acid, or the use of glycolide which is a cyclic dimer of glycolic acid, and therefore **CANNOT** teach that lactide and glycolide are interchangeable. The Examiner's statement that lactide and glycolide are interchangeable without any physical changes in the composition, is not supported anywhere in Fuisz. Again, Fuisz **does not** teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed.

Regarding assertion (ii), that "If lactide and/or glycolide are referred to as polymers in Fuisz reference then they polymers in Applicants instant claimed composition. Lactide and glycolide cannot be monomer in one invention and polymers in another invention," Applicants do not understand the Examiners statements. The Examiner appears to assert that because Fuisz allegedly refers to lactide and/or glycolide as polymers, than they must

be polymers in Applicant's disclosure. Again, claims 29, 50 and 53 have been amended to recite, in part, "…wherein glycolide is a cyclic dimer of glycolic acid." Again, Fuisz **does not** teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed. Likewise, it is well established in the scientific community that lactide is a cyclic dimer of lactic acid. *See* the evidence submitted with the Amendment and Response submitted on October 23, 2009. Regarding Fuisz, Fuisz clearly describes the use of ***polymers*** marketed under the Medisorb trademarks. Nowhere does Fuisz teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed. Applicant's point out that it is CLEAR that Fuisz employs specific POLYMERS marketed under the Medisorb trademark. Applicants again note that the Medisorb polymers are described in Fuisz as ***polymers of lactide and/or glycolide***. Nowhere does Fuisz define lactide itself or glycolide itself as a polymer. Regarding assertion (iii), that Myers also teaches that the glycolide and lactide can be used interchangeably whether it is used in a film or a tampon as described above in length," Applicants note that Myers describes a film that can include ***polymers*** such as poly glycolic acid (PGA), polylactic acid (PLA), and lactide/glycolide copolymer. Myers does not teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as required by the present claims. Further, Applicants strongly traverse the Examiners assertion. The Examiner has ***not*** shown how Myers discloses this. Please *see* the arguments filed in our previous responses of June 2, 2009, particularly pages 14-17, and July 12, 2010, each of which is incorporated herein by reference in its entirety.

Regarding assertion (iv), that "Kluger et al. teaches lactide incorporated in the tampon for the desire pH 5.5 to be achieved the other references teach that the same effect

can be reached by incorporating glycolide," Applicants submit that nowhere do any of Fuisz or Meyers teach or suggest that incorporating lactide in a tampon, let alone incorporating glycolide that is a cyclic dimer of glycolic acid as presently claimed, can achieve the effect of lowering pH to 5.5. None of Fuisz or Meyers teach or suggest that lactide or glycolide have the effect of lowering pH to 5.5.

E. Glycolide and Lactide

Glycolide is a cyclic dimer of glycolic acid and is now claimed as such. Please *see* the arguments set forth in the response filed on July 12, 2010 which are hereby incorporated by reference herein in their entirety. Again, U.S. Patent No. 5,374,743 describes at col. 1, lines 9-11, that "The monomer used is lactide or glycolide which are cyclic dimmers of lactic acid or glycolic acid and which are prepared from lactic acid or glycolic acid." *See also* U.S. Patent Nos. 6,891,048 and 7,235,673 submitted with the Amendment and Response filed on March 20, 2008.

In addition, lactide is a cyclic dimer of lactic acid. *See* http://en.wikipedia.org/wiki/Lactide.

F. Glycolide and Lactide are not Interchangeable

Applicants again emphasize that the present subject matter is directed to a formulation comprising ***glycolide*** that is a cyclic dimer of glycolic acid, as presently claimed, and ***not*** a polymer thereof.

The Examiner is ***again requested to cite authority*** that would establish that

glycolide and lactide are interchangeable, and that glycolide can be used in combination with lactide or separately in a formulation without any physiological effect to the composition, should this rejection be maintained.

The data set forth in the Examples of the present specification clearly establishes that lactide and glycolide ***are NOT interchangeable,*** and that the use of glycolide exhibits unexpectedly superior results over the use of lactide.

Applicants again assert that ***glycolide and lactide are not interchangeable***. Rather, they are ***DIFFERENT*** cyclic esters having ***DIFFERENT*** chemical properties.

Glycolide is a completely different molecule than lactide. Glycolide has a different molecular structure and different properties than lactide. Glycolide is a cyclic dimer of two glycolic acid molecules, while lactide is a cyclic dimer of two lactic acid molecules. The main difference between lactide and glycolide, is that ***glycolide is HYDROPHILIC*** and ***lactide is HYDROPHOBIC***. This is due to the absence, in glycolide, of the two pendant methyl groups which are present in lactide. Thus, glycolide undergoes hydrolysis (and converts into two glycolic acid molecules) much more efficiently and quickly than lactide, for example, during tampon usage. This well-know difference in properties of lactide and glycolide is used to tailor the degradation kinetics of many known artificial implants and medical devices, the most familiar of which are the degradable sutures. Such sutures can be made of copolymers synthesized from lactide (hydrophobic) and glycolide (hydrophilic), the ratio between the two components in the polymer dictates the degradation rate of the polymer, which should be approximately at the rate of tissue healing. In view of the foregoing, it is clear that glycolide and lactide have ***significantly different properties*** and are thus, ***not*** interchangeable.

These differences in properties between lactide and glycolide result in surprising

advantages using glycolide rather than lactide to reduce pH, as supported by the results described in the Examples set forth in the present specification.

G. None of Kluger, Fuisz and Meyers teach the use of Glycolide

Applicants submit that none of Kluger, Fuisz and Meyers, taken alone or together, teach or suggest the use of glycolide that is a cyclic dimer of glycolic acid, as presently claimed. Rather, all of Kluger, Fuisz and Meyers describe the use of polymers of glycolic acid and/or lactic acid. Applicants note Fuisz and Meyers describe that such polymers are marketed under the Medisorb trademarks and also refer to these polymers as ***polymers*** of lactide or glycolide. Regardless, it is clear that the Medisorb compositions are POLYMERS and are not glycolide that is a cyclic dimer of glycolic acid, as required by the present claims.

In view of the foregoing, it is submitted that nothing in Kluger, Fuisz, and Meyers, taken alone or together, renders claims 29-47 and 50-60 obvious within the meaning of 35 USC § 103. Thus, it is submitted that claims 29-47 and 50-60 are patentable over the combination of Kluger, Fuisz, and Meyers. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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